

Reply:

Dr Sherlock asks for clarification on the approach adopted by the European Committee on Hyperbaric Medicine (ECHM) to assessing evidence for establishing indications for hyperbaric oxygen treatment (HBOT).¹

Firstly, regardless of the strict process of editing and proof-reading of tables included in the above-mentioned publication, we received comments from some readers that identified imperfect layout of Table 1 and incorrect layout of Table 2 which significantly changed the conclusions to be drawn from them. This concerned both the details of the methodology used and description of the ECHM recommendations and associated levels of evidence. Therefore, those tables are republished in their correct forms in this issue, hoping that this will explain at least some of the doubts and misunderstandings.² Both the Editor and ourselves apologise for these errors of publication.

Secondly, in the ECHM Consensus Conference methodology, we scored the evidence for clinical studies requiring double-blind randomised controlled trials (RCT) as Level A and B when, at the same time, some scoring scales require simply 'RCT', as correctly pointed out by Dr Sherlock. Long experience in organising evidence based medicine (EBM) meetings and discussions has taught us that RCTs that are not double blinded are often criticised as having serious potential bias and so are denied as level A evidence. Although we acknowledge that double blinding a clinical study in HBOT is a source of difficulty, we chose *a priori* to consider only double-blinded RCTs in our grading scale to avoid endless discussions about this potential bias. We are well aware that doing so means that Level A evidence is a difficult target for the hyperbaric community.

We agree that many evidence scoring systems have a low level of inter-observer agreement. This is why we treat the Consensus Conference as a valuable tool that provides a better opportunity for discussing the evidence than analysis by a small group of 'experts'. This is because the whole process is transparent and available to all participants' comments and input. The final process of voting by the audience after the general discussion thus truly reflects the position of the professional hyperbaric community in Europe on the issued recommendations. By these two mechanisms, the blind application of disputable evidence scoring systems may be avoided or, at least, decreased.

Thirdly, the problem of 'sham' treatments in hyperbaric research has been raised. While this has been discussed many times in the past, hyperbaric research is not the sole field where such sham treatment raises some difficulty. Surgery is probably the best example where RCTs with control arms utilising sham surgical procedures (possibly including the administration of anaesthesia) are rare and can raise major ethical problems. Nevertheless, from an EBM viewpoint, the

difficulty of designing a double-blind study is never taken into account during evaluation of clinical studies.

Finally, Dr Sherlock pointed out her doubts on the recommendations issued by the ECHM on idiopathic sudden sensorineural hearing loss (ISSHL). While there is no possibility to cite here the full experts' report on that issue presented during the conference, we understand that a detailed report from the Conference is being prepared for publication. In brief, the strength of evidence has been scored as Level B, in general agreement with the last Cochrane review and the UHMS Committee report.^{3,4} Based on this level of evidence, the Type 1 recommendation was issued with the agreement of the large majority of the Consensus Conference participants.

References

- 1 Mathieu D, Marroni A, Kot J. Tenth European Consensus Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment. *Diving Hyperb Med.* 2017;47:24-32.
- 2 Correction. *Diving Hyperb Med.* 2017;47:131-2.
- 3 Bennett MH, Kertesz T, Perleth M, Yeung P, Lehm JP. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus. *Cochrane Database Syst Rev.* 2012;10:CD004739.
- 4 Weaver LK, editor. *Hyperbaric oxygen therapy indications*, 13th Ed. North Palm Beach, FL: Best Publishing Company; 2014.

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Key words

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